K010164

APR - 9 2001

## Section 2 Summary and Certification

### 510(k) Summary of Safety and Effectiveness

**Date:**
January 9, 2001

**Submitter:**
GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

**Contact Person:**
Karen Webb
Sr. Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: (414) 362-3329
Fax: (414) 371-3736

**Device: Trade Name:**
ICG Module

**Common/Usual Name:**
Impedance Plethysmograph

**Classification Names:**
21 CFR 870.2770 Impedance plethysmograph

**Predicate Devices:**
K974725 CardioDynamics BioZ.com System

**Device Description:**
The ICG Module is part of a modular system that measures and processes a patient's hemodynamic parameters using non-invasive bioimpedance technology. Monitoring is accomplished by injecting a high frequency, low amplitude alternating electrical current through the thorax between a pair of sensors placed on the neck and another pair placed on the mid-axillary line at the xiphoid process level.

The ICG Module works as a component of a GE Medical Systems *Information Technologies* host monitoring system and does not function on its own. The ICG Module provides information obtained from the sensors to the bedside monitor for display of impedance waveforms and hemodynamic parameters.

**Intended Use:**
The ICG Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The ICG Module is intended to monitor hemodynamic parameter data on adult patients within a hospital or facility providing patient care.

Hemodynamic parameter data includes: cardiac output, cardiac index, stroke volume, stroke index, systemic vascular resistance, systemic vascular resistance index, heart rate, thoracic fluid content, velocity index, acceleration index, left cardiac work index, pre-ejection period, left ventricular ejection time, left stroke work index, and systolic time ratio.

**Technology:**
The ICG Module employs the same functional scientific technology as its predicate devices.

Test Summary:

The ICG Module and its host patient monitoring system comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the ICG Module:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the ICG Module is as safe, as effective, and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Ms. Karen Webb
Senior Regulatory Affairs Specialist
GE Medical Systems
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K010164
Trade/Device Name: ICG Module
Regulation Number: 870.2770
Regulatory Class: II (two)
Product Code: DSB
Dated: January 9, 2001
Received: January 18, 2001

Dear Ms. Webb:

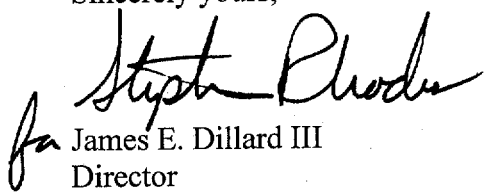
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010164 Unknown; 510(k) filed on January 9, 2001

Device Name: ICG Module

Indications for Use:

The ICG Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The ICG Module is intended to monitor hemodynamic parameter data on adult patients within a hospital or facility providing patient care.

Hemodynamic parameter data includes: cardiac output, cardiac index, stroke volume, stroke index, systemic vascular resistance, systemic vascular resistance index, heart rate, thoracic fluid content, velocity index, acceleration index, left cardiac work index, pre-ejection period, left ventricular ejection time, left stroke work index, and systolic time ratio.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010164

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)